

2011 Public Health Preparedness Summit

High Priority Tools for Public Health Emergency Legal Preparedness

Toward Elimination: Developing Legal Resources to
Prevent and Control TB

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History and Epidemiology of Tuberculosis

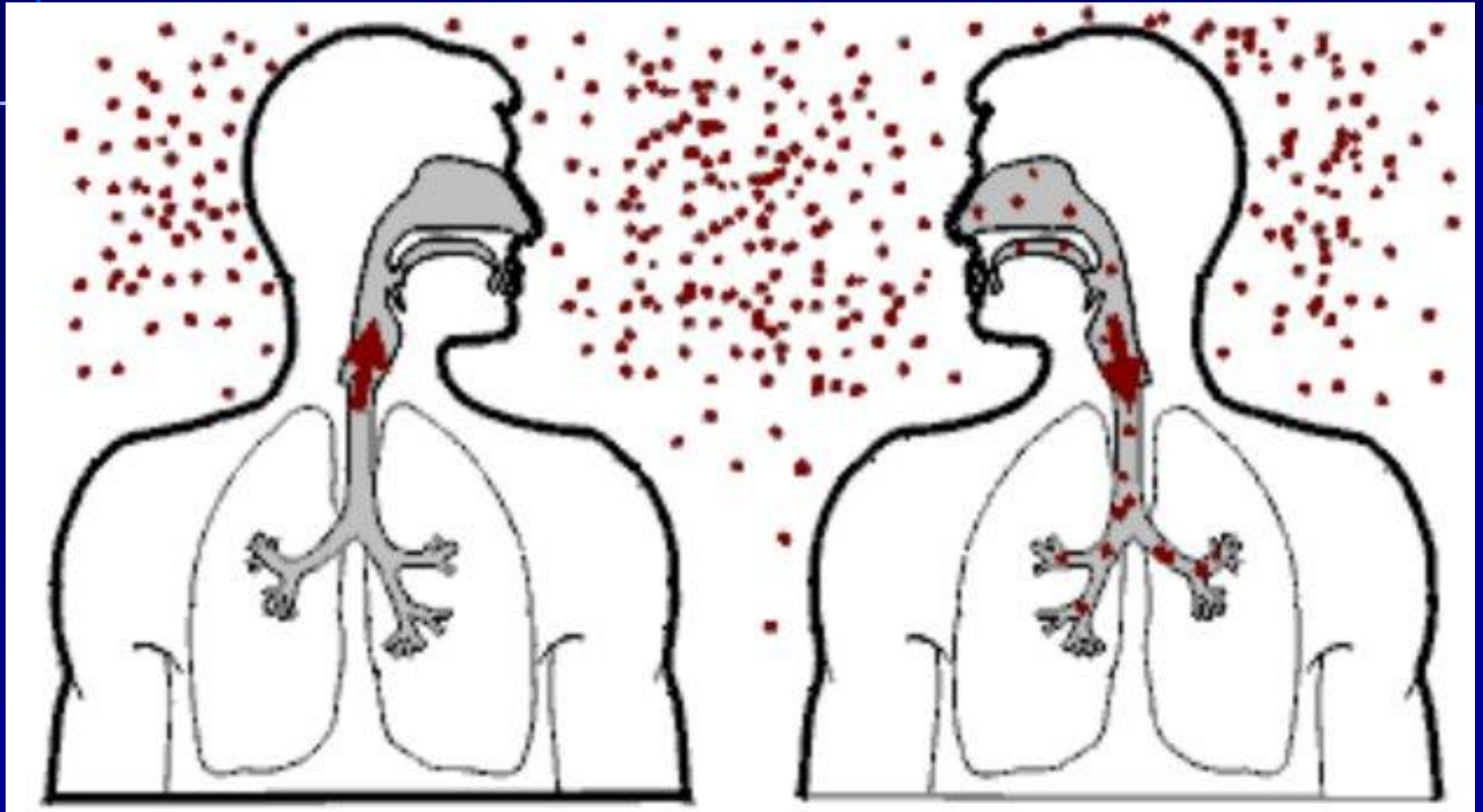


What is Tuberculosis?

- TB is a disease caused by germs that are spread from person to person through the air
 - Pulmonary
 - Extrapulmonary
- TB germs are put into the air when a person with TB disease of the lungs or throat coughs, sneezes, speaks, or sings

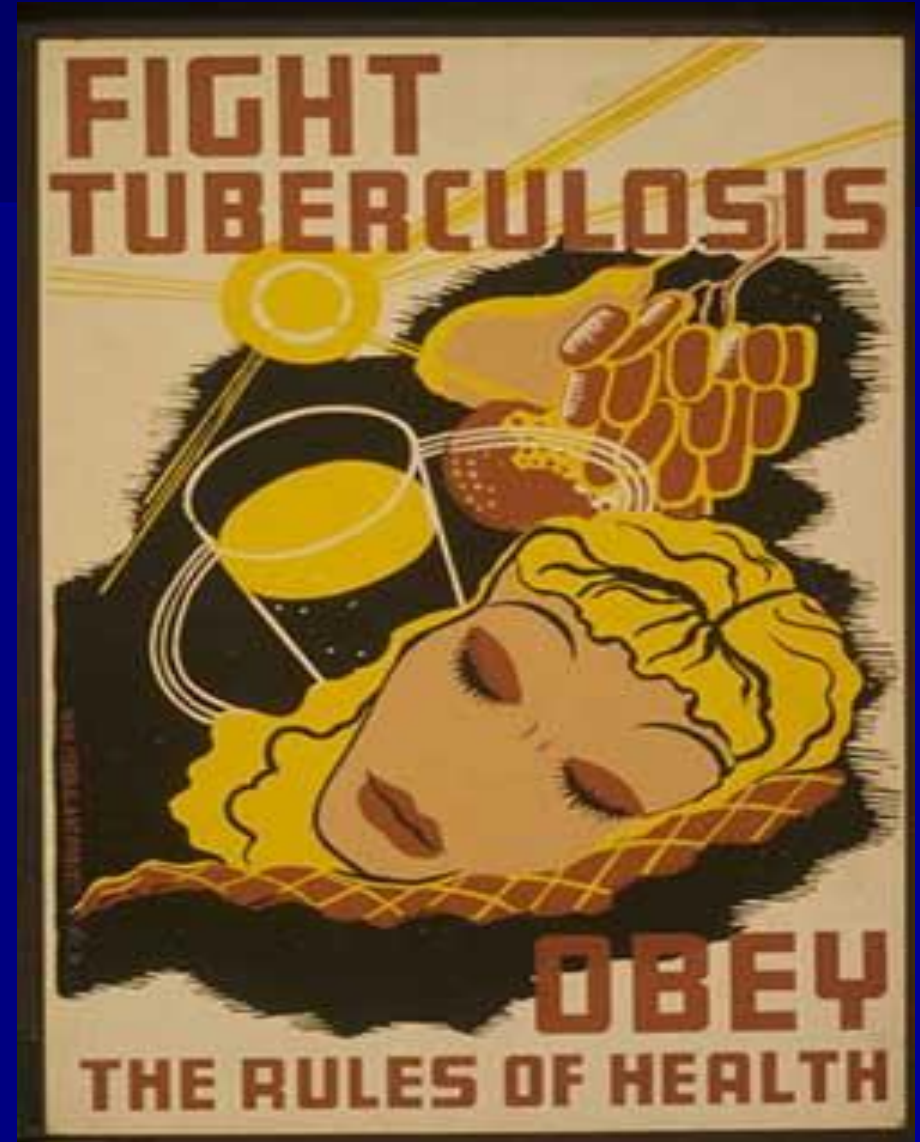


Transmission of TB

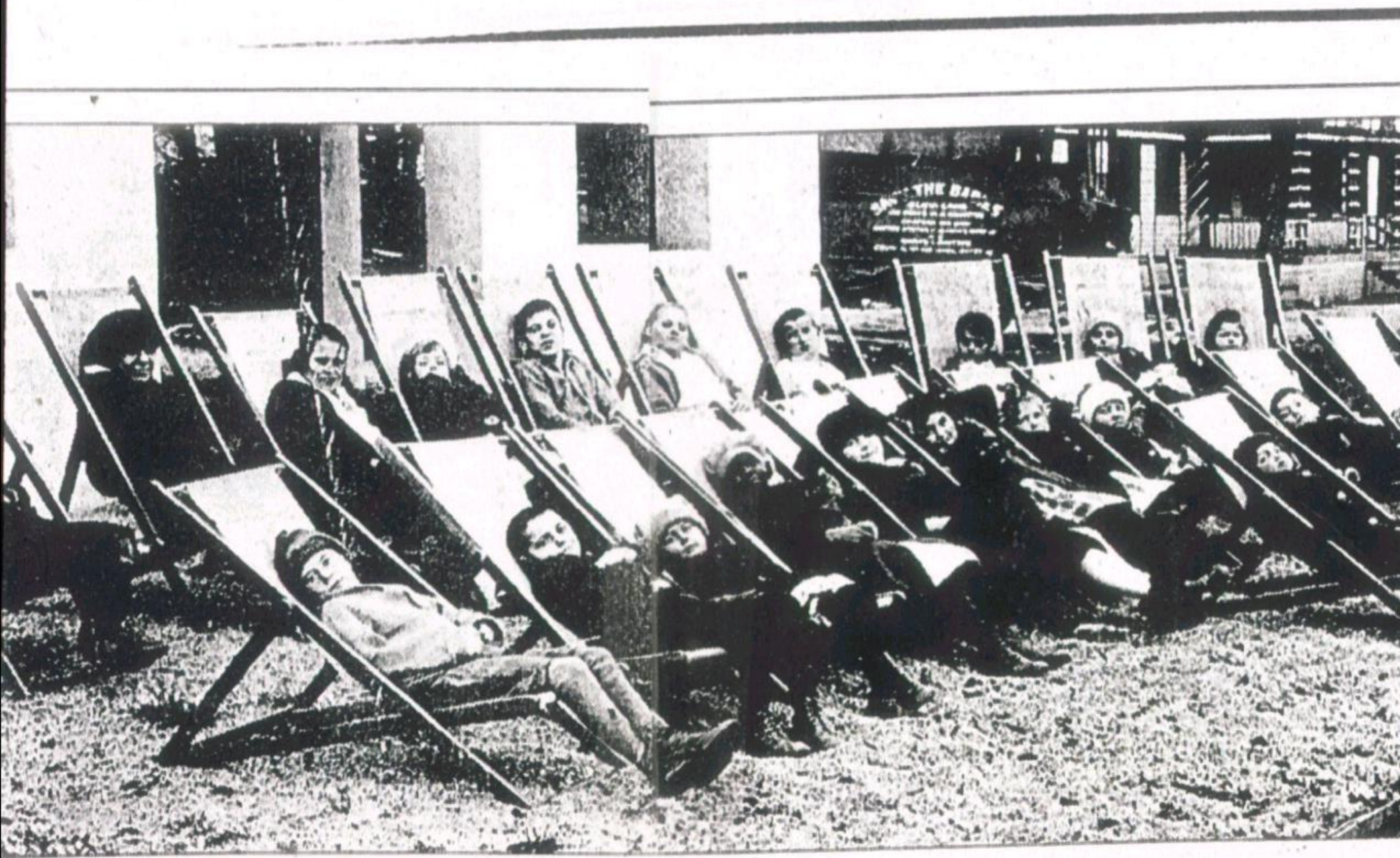


History of Tuberculosis

- 1882 - Robert Koch discovered staining method to detect *Mycobacterium tuberculosis*
- Early 1900s – TB sanatoria became common in U.S.
- 1952 – discovery of first-line TB drug isoniazid



Sunny Acres Sanatorium—Cleveland, OH 1918

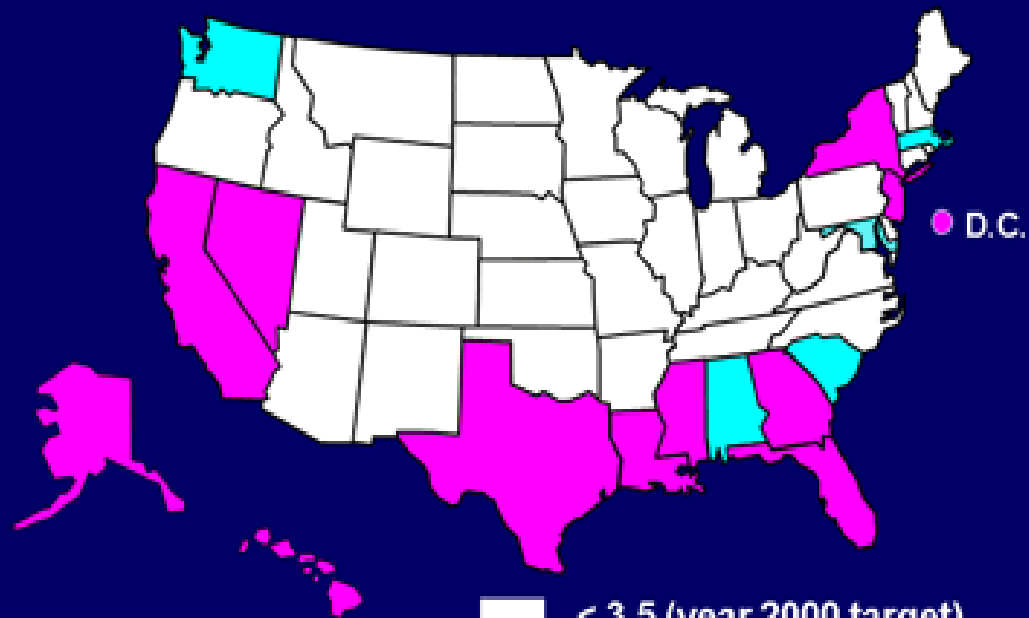


Early in the century, tuberculosis was a dreaded scourge. These children were being treated at Sunny Acres Sanatorium in

Tuberculosis in the United States

- Latent TB vs. active TB
- 11,540 TB cases reported in the U.S. in 2009
- Largest decline since national reporting began in 1953

TB Case Rates,* United States, 2009



*Cases per 100,000.



Legal Framework for TB Control



U.S. Constitution – Sources of Power

- Federalism: the relationship and distribution of power between individual states and national government
- The Constitution authorizes some federal public health-related activities (Art. I, Sec.8)
 - Commerce Clause
 - Tax and Spend Clause
- States retain primary authority over public health through the 10th Amendment



State Public Health Authority

- Tenth Amendment: *The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people*
- States exercise “police powers” to protect the public’s health
- Police powers defined: Powers exercised by the states to enact legislation and regulations to protect the **public health**, welfare, and morals, and to promote the common good



Types of Legal Authority

- The following laws serve as mechanisms by which to control the spread of TB:
 - Statutes: enacted by state legislatures
 - Regulations: promulgated by agencies, usually more detailed than statutory provisions
 - Case Law: decisions by judges interpreting laws; at the appellate level, creates binding precedent



State TB Control Laws



State TB Control Provisions

- TB control law varies considerably from state-to-state
- State statutory provisions and regulations usually address the following areas of TB control:
 - Case identification
 - Management of TB cases
 - Other Protections



Case Identification

- Reporting Requirements
 - Persons required to report
 - Time frame for reporting
 - Penalty for failure to report
- Screening
 - Prerequisite for certain types of employment
 - Exclusion from certain places
 - High-risk congregate settings



Management of TB Cases (1)



- Investigation of TB cases
 - Examination
 - Contact tracing
- Provision of treatment
 - Immediate treatment
 - Compel treatment
 - Directly observed therapy
- Penalty for nonadherent patients



Management of TB Cases (2)

- Detention in treatment facility
 - If involuntary, court order may be issued
 - Due process protections
 - Length of detention
- Restrictions for persons with active TB
 - Isolation
 - Restriction from certain activities
- Treatment facilities
- Financing of treatment



Other Protections

- Religious exemptions for treatment
- Confidentiality, protection of identifiable health information
- Specific due process procedures
- Anti-discrimination provisions



Constitutional Issues



Constitutional Issues

- Public health officials do not have unlimited authority to control TB
- State laws must comport with constitutional provisions
- Constitutional provisions that may arise in TB control law include the 1st, 4th, 8th, and 14th Amendments



Fourteenth Amendment

Due Process Clause

- 14th Amendment Due Process Clause: “...*nor shall any State deprive any person of life, liberty, or property, without due process of law*”
 - **Substantive due process:** The government must have adequate justification for laws or other official actions that affect life, liberty, or property
 - **Procedural due process:** The procedures the government uses when depriving a person’s liberty must be fair and reasonable



Fourteenth Amendment Substantive Due Process

- Case Example: *Newark v. J.S.*
 - Nonadherent patient
 - Liberty interest in freedom from confinement
 - Controlling interest in protecting public health
 - Involuntary hospitalization the least restrictive means



Fourteenth Amendment Procedural Due Process

- Case Example: *Greene v. Edwards*
 - Involuntary commitment of active TB patient
 - Lack of reasonable access to legal counsel
 - Articulation of due process procedural elements
 - Written notice
 - Right to counsel
 - Right to be present, cross-examine witnesses
 - Standard of proof – clear & convincing evidence
 - Right to a transcript of the proceeding



Fourteenth Amendment Equal Protection Clause (1)

- The 14th Amendment of the U.S. Constitution also prohibits States from denying “any person within its jurisdiction the **equal protection** of the laws.”
- The Equal Protection Clause is different from the Due Process Clause in that it focuses on the rights of groups rather than individuals
 - Individuals within the group are certainly protected
 - may assert rights
- Government may not arbitrarily discriminate against a group of people just because they fall into a particular category



Fourteenth Amendment Equal Protection Clause (2)

- Case Example: *Jew Ho v. Williamson*
 - Quarantine of Chinatown district during bubonic plague outbreak
 - Residents of Chinese descent subject to quarantine but white residents/business owners were not
 - Violation of equal protection because quarantine was underinclusive



First Amendment (1)

- 1st Amendment: “*Congress shall make no law respecting an establishment of religion, or prohibiting the **free exercise** thereof.*”
- An individual’s right to free exercise of religion is not violated if the law is **neutral** and of **general applicability**



First Amendment (2)

- Case Example: *Washington v. Armstrong*
 - Board of regents required all students to submit to chest X-ray examination prior to registration
 - Appellant student requested exemption, citing religious views
 - Court held in favor of board of regents
 - Court weighed the public health interest of students and university employees against First Amendment interest of individual student
 - “Infringement of appellant’s rights is a necessary consequence of a practical attempt to avoid the danger”



Fourth Amendment

- The 4th Amendment prohibits ***unreasonable searches and seizures***
- Courts evaluate the reasonableness of a search by weighing the intrusion into individual privacy against the government's need for information
- Case Example: *Washington v. Cambra*
 - Prison officials subjected appellant to TB test against his will
 - Court held that TB test is considered a search, but prison's TB testing policy was reasonably related to legitimate goal of preventing spread of TB



Eighth Amendment

- 8th Amendment: “*Excessive bail shall not be required, nor excessive fines imposed, nor **cruel and unusual punishments inflicted***”
- Case Example: *McCormick v. State*
 - Appellant prisoner tested positive for TB while in prison
 - Given the choice of isolation or treatment
 - Court held appellant failed to meet burden that prison officials were deliberately indifferent to his serious medical needs



TB Control Law in Practice

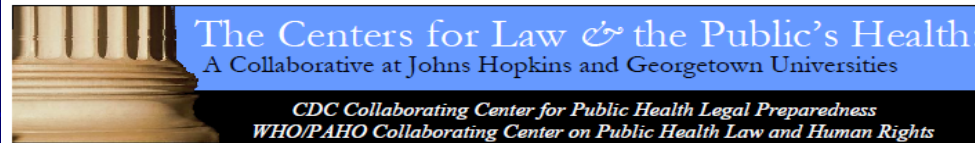
- Legal advisors to public health practitioners may be within an agency, such as the state health department*
- State health officers and their legal counsel work together to exercise state police powers
- Legal mechanisms by which to control TB can take many forms



Legal Resources to Prevent and Control TB



1. Review / Characterization of Express Laws for TB Control



Express Tuberculosis Control Laws in Selected U.S. Jurisdictions¹

A Report to the
Centers for Disease Control and Prevention (CDC)

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As of October 1, 2008

Disclaimer – Information in this document does not represent the official legal positions of the U.S. Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention/HHS, or state or local governments, and is not meant to provide specific legal guidance or advice. Thus, users of this report, including state and local officials, should consult with their state and local attorneys and legal advisors for a more complete review of laws and policies pertaining to TB control.



1. Review / Characterization of Express Laws for TB Control

- Goal: To examine, organize, and characterize legislative, regulatory, or judicial (case) laws across 25 select jurisdictions that *expressly* relate to the control of cases of TB, MDR-TB, or XDR-TB through state or local health departments, other governmental actors, and private sector partners
- Caveat: Focus was on *express* TB control laws and, therefore, excluded general communicable disease laws
- Available on PHLP, DTBE, and NTCA websites



2. Scenario Tool for Assessing Understanding / Sufficiency of TB Control Laws

CDC Scenario-Based Assessment: Understanding and Sufficiency of States' TB Control Laws

Generic Version – 31 October 2008

Developed by:

**Public Health Law Program
Division of Tuberculosis Elimination
Division of Global Migration and Quarantine**

Objectives

This hypothetical scenario has been designed to assist persons in state agencies and/or other jurisdictional settings with roles and responsibilities for controlling and preventing the spread of tuberculosis to explore their understanding of, and to identify potential limitations of or gaps in:

- The viability and sufficiency of jurisdiction-specific legal authorities for limiting or preventing the transmission of TB through fundamental steps, including: screening and identification of cases; contact investigation; investigation of known or suspect cases; reporting of cases; treatment (including directly-observed treatment); the use of specific containment measures (e.g., isolation, quarantine, and other restrictions); and measures for ensuring the legal protections of persons with cases of TB, such as procedural due process, health information privacy, anti-discrimination, respect for religious beliefs, and other individual safeguards and protections.
- Legal authorities, requirements and options for coordination of multi-jurisdictional (intrastate, interstate, and international) TB case management, including screening for infectiousness before travel or movement outside of the original jurisdiction, managing risk of infection during travel, and ensuring continuity and completion of treatment (and coverage of associated costs) before and after travel.
- Legal authorities for coordination of control efforts (e.g., identification, reporting, contact investigation, and treatment of TB cases), across key sectors, including public health, health care providers, and public safety / law enforcement, and in various settings (e.g., schools, correctional facilities, nursing homes, mental health facilities, and homeless shelters).
- Legal authorities in relation to the infectiousness of smear-negative / culture-positive patients.

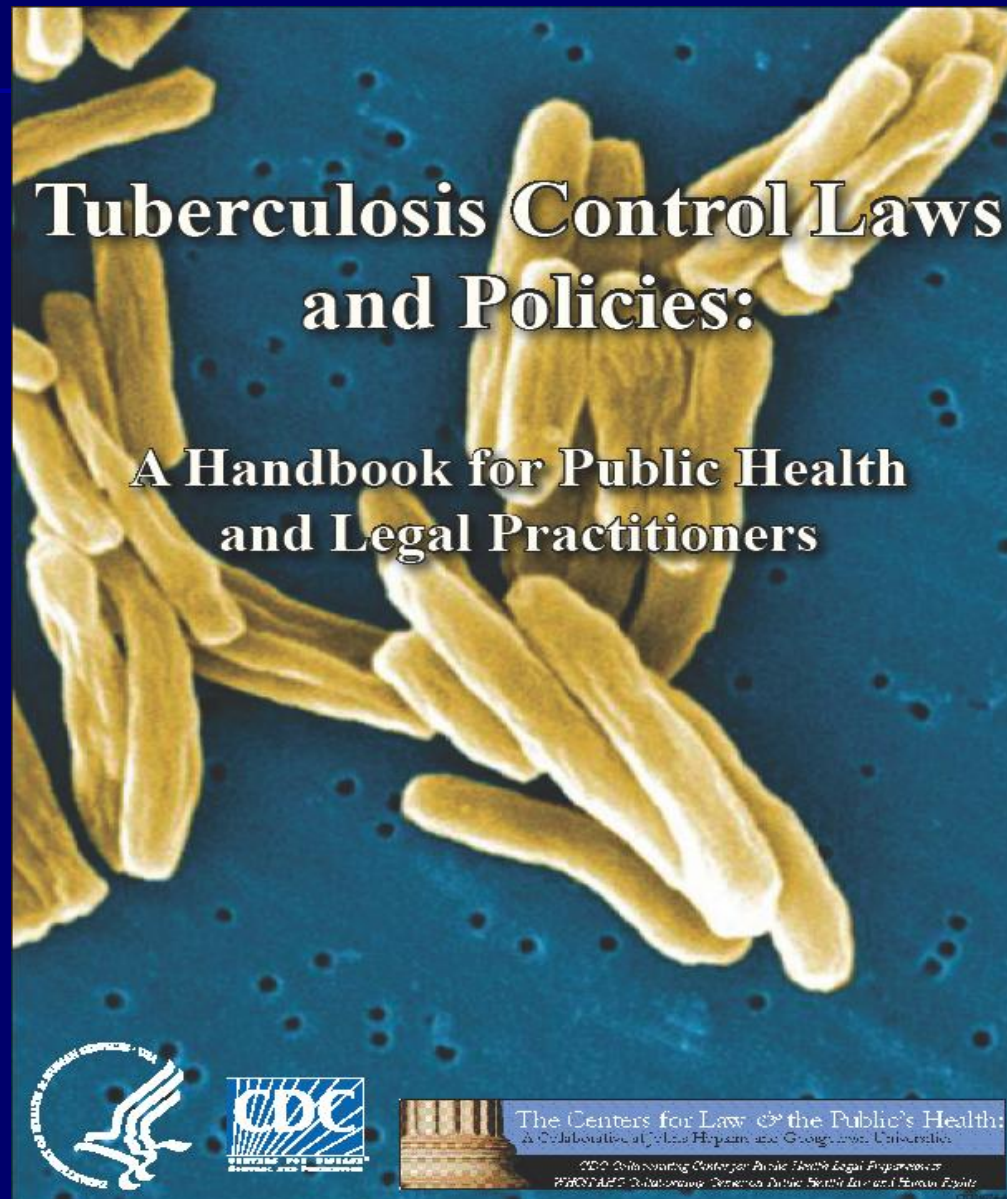


2. Scenario Tool for Assessing Understanding / Sufficiency of TB Control Laws

- Convened officials from relevant sectors to work through a scenario designed to:
 - Assess participants' understanding and sufficiency of laws for TB control
 - Identify potential gaps in legal authority that might assist in informing development of the model act on TB control
- Selected states and pilot implementation:
 - Kansas: May 23, 2008
 - Florida: May 28, 2008
- Developed accompanying implementation guidance for any jurisdiction anticipating use of the scenario.
- Available on PHLP, DTBE, NTCA, and other websites



3. Handbook on TB Control Law for State TB Control Practitioners



The Centers for Law & the Public's Health:
A Collaboration at Johns Hopkins and Georgetown Universities
CDC Collaborating Center for Public Health Legal Preparedness
PHSLAP's Collaborating Centers: Public Health Law and Human Rights



4. Handbook on TB Control Law for State TB Control Practitioners

- Audiences: Public health practitioners active in TB control at local, state, and tribal levels, and their legal counsel
- Focus: Pertinent local, state, and tribal law, and essential information on federal and international law (e.g., IHR)
- The Handbook and a companion instructional slide unit are available on PHLP, DTBE, and NTCA websites.



4. Menu of Suggested Provisions for State Tuberculosis Prevention and Control Laws (Menu)

- Purpose: To be of immediate practical value to public health officials and their legal counsel in the enactment, promulgation, amendment, or implementation of TB prevention and control laws in a variety of jurisdictions.



4. Menu - Development of the Draft

Summer-Fall 2009

- Conducted research on all 50 states' (plus the District of Columbia and New York City) TB prevention and control statutes and regulations.
- Created categories based on the 1993 MMWR article on state TB control laws, and current issues in TB prevention and control.
- Returned to each state's TB control (or general communicable disease control) laws to review and place them into categories.



4. Menu - Workshop

Winter 2009

- Workshop conducted by the Division of Tuberculosis Elimination and the Public Health Law Program on February 4-5, 2010.
 - Participants included state and local TB program staff and their legal counsel, representatives from partner organizations, and CDC staff.
- Purpose of the Workshop: To obtain feedback from participants on whether provisions should be added or deleted from the draft Menu, and what laws have been effective in their jurisdictions.



4. Menu - Development of Final Version

- Revised the draft Menu based on comments received at the February Workshop, the ACET meeting, and the APHL TB Steering Committee's review.
- Drafted an introduction and descriptive notes to accompany each section.
- Circulated the revised draft among workshop participants for final review.
- Disseminated the Menu to the NTCA Board and to ACET.



4. Menu - Accessibility

- <http://www.cdc.gov/tb/programs/Laws/default.htm>
 - Interactive version of the Menu
 - PDF file of the Menu
 - Fact Sheet describing the Menu



Case Vignettes



Case Vignettes (1)

- Lawful permanent resident with known MDR TB under local isolation order in Camden County , New Jersey flies against medical advice to San Francisco
- Patient is placed on DNB and intercepted by TSA in San Francisco airport attempting to board an international flight to China
- Who has “jurisdiction” over this patient?
- Who should pay for the costs of isolating this patient?



Case Vignettes (1)



- What would you do?
- End result:
 - Patient escorted to hospital in San Francisco under a local isolation order
 - CDC issues federal order and uses CDC chartered aircraft to escort patient back to home state of New Jersey
 - Because of short duration of flight, patient determined not to pose a public health risk to flight crew
 - Camden County public health officials agree to pay for patient's medical treatment
 - Camden County exploring possibility of whether patient as a Lawful Permanent Resident qualifies for Medicaid



Case Vignettes (2)

- You are a public health official in West Carolina, a state that does not have a medical facility in which to treat patients with infectious TB.
- There is a medical facility for TB patients in East Virginia, a neighboring state.
- This facility suggests that you enter into a Memorandum of Understanding with them to transfer patients to the facility, across state lines.
- You ask legal counsel to the health department if you have legal authority to enter into such an agreement.



Case Vignettes (2)



- What would you do?
 - If legal counsel determines that there is existing legal authority to enter into the agreement, you might want to consider looking here for examples of agreements:
<http://www2.cdc.gov/phlp/mutualaid/MutualResources.asp>
 - If legal counsel determines that there is no existing legal authority to enter into this agreement, here is the section of the Menu that might help in drafting legislation:
<http://www.cdc.gov/tb/programs/Laws/default.htm>



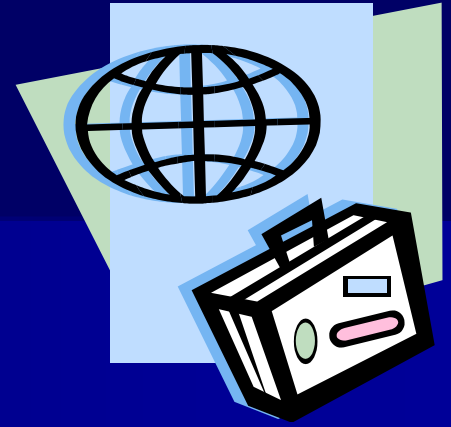
Case Vignettes (3)

- Foreign citizen enters U.S. illegally; detained at airport by Customs & Immigration after discovery of suitcase full of TB drugs
- Patient granted “medical parole” by CBP after confirmation of MDR TB status
- Patient served with a federal isolation order, then detained in a hospital under a local order
- Who is responsible for this patient’s hospital bills?
- Is this an immigration matter or a public health matter?



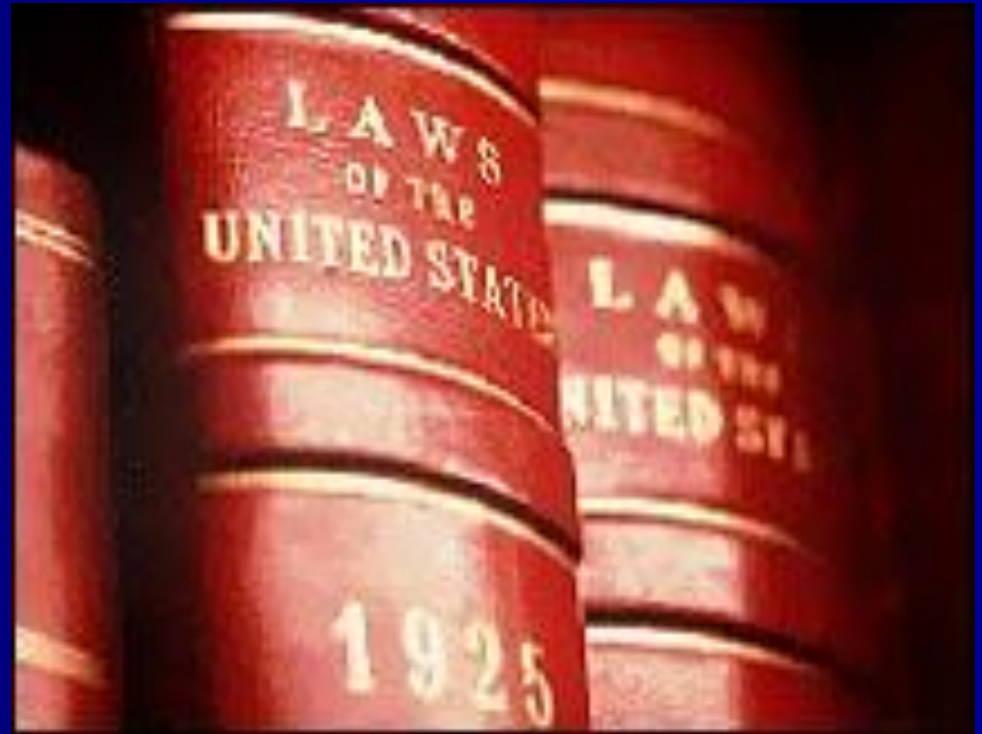
Case Vignettes (3)

- What would you do?
- End result:
 - Patient was treated in U.S. by ICE until continuity of care in home country could be established
 - CDC reached an agreement with the hospital to pay a portion of the expenses
 - CDC working to develop a cost-sharing policy



Questions?

Thank you for your
attention!



Acknowledgements

- Division of Tuberculosis Elimination, CDC
- Public Health Law Program, CDC
- Division of Global Migration and Quarantine, CDC
- Office of the General Counsel, CDC
- National Tuberculosis Controllers Association
- Advisory Council for the Elimination of Tuberculosis
- National Association of County and City Health Officials
- Association of State and Territorial Health Officials

